

tunnelvision™

Endoscopic Soft Tissue Release System

Endoscopic Carpal Tunnel Release Surgical Technique Guide



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TUNNELVISION™ INTENDED USE, INDICATIONS, CONTRAINDICATIONS

INDICATIONS FOR USE

The TunnelVision Endoscopic Soft Tissue Release System is indicated for use in minimally invasive ligament or fascia release:

- Carpal tunnel release in the wrist
- Cubital tunnel release in the elbow

CONTRAINDICATIONS

The TunnelVision Endoscopic Soft Tissue Release System should not be used on uncooperative or mentally incompetent patients who are unable to follow the postoperative regiment. Anatomical abnormalities affecting safe and effective use of the system, such as those impairing tissue visualization, should be identified and an alternative procedure completed. Specific carpal tunnel and cubital tunnel contraindications and cautions are listed below.

Carpal Tunnel

The TunnelVision System should not be used in patients with severe or significant abnormalities of the surgical site area, including those with an aberrant branch of the median nerve, either ulnarly or transligamentously, that cannot be visualized, missing or floating hook of the hamate, distal radial deformities, unusually tight carpal tunnel, rheumatoid arthritis, or other carpal synovitis.

Cubital Tunnel

The TunnelVision System should not be used in patients with known abnormalities of the elbow, including deformities, severe medial epicondylitis, rheumatoid, bursitis, unusually small elbow, or other synovitis conditions. Congenital anatomical abnormalities, such as abnormalities of the medial elbow and ulnar nerve subluxation, are contraindicated.

SYSTEM OVERVIEW

The TunnelVision Endoscopic Soft Tissue Release System consists of an endoscope paired with a handpiece designed to secure a single-use blade assembly. The carpal tunnel device connects to standard video camera and light sources commonly used for endoscopic or arthroscopic procedures. It is intended for dry use, without the addition of fluids or insufflation gases.

Carpal Tunnel Procedure Overview

The surgeon creates an approximately 1cm wide transverse incision in the proximal wrist flexion crease and introduces the disposable blade assembly into the carpal tunnel. Viewing the deep side of the transverse carpal ligament through the endoscope camera, the surgeon depresses the trigger on the handpiece to elevate the blade. The ligament is cut as the instrument is withdrawn in a retrograde direction.

Cubital Tunnel Procedure Overview

The surgeon creates an approximately 3cm longitudinal incision between the medial epicondyle and olecranon and introduces the disposable blade assembly into the cubital tunnel. Viewing the roof of the cubital tunnel fascia through the endoscope camera, the surgeon depresses the trigger on the handpiece to elevate the blade. The fascia is cut as the instrument is withdrawn in a retrograde direction.

ADDITIONAL INFORMATION

The endoscopic procedures for which TunnelVision is indicated should only be attempted after the surgeon has been trained at a TunnelVision or Hand Biomechanics Lab workshop, a comparable device workshop, or by a qualified training surgeon or trained on a comparable device. Operating room staff should review the TunnelVision Instructions for Use prior to setting up this system.

For detailed assembly, cleaning, and sterilization steps and additional Warnings and Cautions, consult the TunnelVision Instructions for Use, available at <https://tunnelvisionectr.com>.

TUNNELVISION™ INSTRUMENTS AND ACCESSORIES

- A) TunnelVision Handpiece _____ (REF 146500)
 - B) Storz/Olympus Light Post Adapter _____ (REF 245700)
 - C) Wolf/Dyonics Light Post Adapter _____ (REF 245800)
 - D) TunnelVision Endoscope _____ (REF 145600)
 - D) TunnelVision Endoscope (Refurbished) _____ (REF 145600-R)
 - E) HBL Blade Assembly _____ (REF CTR-455)*
 - F) Synovial Elevator _____ (REF 246100)
 - G) Small Dilator _____ (REF 245900)
 - H) Medium Dilator _____ (REF 246000)
 - I) Coequal Dilator _____ (REF 246300)
 - J) TunnelVision Sterilization Tray _____ (REF 146400)
- * sold separately



NOTE: HBL Blade Assemblies (E) are sold separately and provided sterile via gamma irradiation. These are single-use devices.

WARNING: All other system devices are provided non-sterile and should be reprocessed before first use and every use.

GLOSSARY OF SYMBOLS

Symbol	Reference	Description	Standard
	2502	Indicates the product has been gamma irradiated for sterilization.	ISO 15223-1:2021
	0434A / 0434B	Indicates caution is suggested.	
	1051	Indicates the product is single-use.	

WARNINGS AND CAUTIONS

- **WARNING:** Do not use the disposable blade assembly if the sterile packaging is open or damaged.
- **WARNING:** If the blade fails to retract while inside the carpal or cubital tunnel, keep it in-situ and release the locking screw to separate the assembly from the handpiece. If the blade remains elevated, keep it in place and convert to an open procedure.
- **WARNING:** All other system devices are reusable and sent non-sterile and should be sterilized before first use and every use.
- **WARNING:** Failure to follow the Surgical Technique may result in permanent injury to the patient. If issues arise while performing this technique, such as unanticipated anatomical anomalies, poor visibility, difficulty identifying anatomy, or questions concerning technique or instrumentation, the surgeon should abandon the endoscopic carpal tunnel release and convert to an open carpal tunnel release.
- **CAUTION:** Reusable components must be cleaned and sterilized before every use, including first use.
- **CAUTION:** DO NOT exceed a temperature of 280°F (138°C). (Sterilization)
- **CAUTION:** Other sterilization systems/methods have not been tested and are not recommended.
- **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician or hospital.

PREPARATION AND PROCEDURE SETUP

The following devices and equipment are needed in the sterile field prior to surgery.

CAUTION: Endoscopes are fragile.

INSTRUMENTATION

Hand Biomechanics Lab TunnelVision System

- TunnelVision Handpiece
- TunnelVision Endoscope with Light Post Adapters
- Synovial Elevator, Small Dilator, Medium Dilator, and Coequal Dilator
- HBL Blade Assembly, sold separately

Recommended Facility Provided Equipment

- Endoscopy tower (camera and light source)
- 2 double-pronged skin hooks
- 2 Senn rake retractors
- 2 Ragnell right angle retractors
- Adson forceps
- Hemostat
- Tenotomy scissors
- Scalpel handle with #15 blade
- Sterile skin marking pen
- Antifog solution or wipes
- Lead hand or rolled towel



PRIOR TO SURGERY

Before the patient is brought into the surgical suite, the Hand Biomechanics Lab® TunnelVision™ System should be checked for correct operation, which includes blade elevation and retraction and a clear video image. Turn on the camera, light source and monitor. Adjust white balance using a white diffuse cloth or sponge and then lay a blue or green towel on the window, using the fabric of the towel to set the light intensity and focus on the mid and distal portion of the window. Observe for any sign of fogging. Fogging prior to insertion into the patient's body signifies moisture or water in the blade assembly. Fogging after insertion into the carpal tunnel may be condensation caused by the temperature difference between the scope and the patient's body or could signify excess fluid inside of the carpal tunnel. A fuzzy or darkened view could signify a damaged endoscope, which would require the scope to be returned to Hand Biomechanics Lab for service. The positioning of the equipment relative to the operating table and surgeon, including the instruments and monitor, should be assessed and adjusted as necessary after the arm is prepped and draped.

SURGICAL SUITE SETUP

The surgical suite should be arranged such that the surgeon has an optimal view of the video monitor and is properly oriented to the patient's operative hand. The surgeon should be able to easily shift their gaze from the surgical field to the video image.

The surgeon should situate themselves such that the TunnelVision handpiece, held naturally in the hand, easily aligns the blade assembly with the optimal path from the ulnar side of the carpal tunnel to the base of the ring finger. This path minimizes the risk of median nerve injury. Surgeons generally position themselves to allow the handpiece to be held in their dominant hand, e.g. right-handed surgeons taking an axillary position for right carpal tunnel release (holding the instrument in their right hand) and cephalic position for a left release, while left-handed surgeons typically reverse this.

The endoscopy light source, camera equipment and monitor are most commonly located across the hand table from the surgeon on a wheeled cart, with the endoscope cable secured to a drape proximal to the patient's operative hand. The surgeon's assistant should be positioned opposite the surgeon, with care taken not to obstruct the surgeon's view of the monitor, with the patient's operative hand between them. A scrub nurse may optionally be present at the end of the table, at the surgeon's discretion.

PATIENT PREPARATION

The arm is prepped and draped in the usual sterile fashion. A lead hand may be used, or a rolled towel may be placed under the patient's wrist based upon surgeon preference. Care should be taken to avoid pressure on the ulnar nerve at the elbow.

An upper arm tourniquet is preferred as forearm tourniquets will obstruct the scope and guide as well as put increased tension on the flexor tendons, crowding the carpal canal. Using an Esmarch bandage, the upper extremity should be exsanguinated prior to inflation of the tourniquet.

ANESTHESIA

Options include general, MAC or local and regional anesthesia. Some surgeons prefer to perform the technique under general anesthesia to reduce the risk of the patient gripping and/or pronating during the procedure. General anesthesia is recommended for surgeons who have limited experience with the ECTR procedure. Due to the tendency of local anesthetic to increase tissue fluid, the likelihood of the endoscope lens becoming obscured by fluid or fogging increases. Therefore, surgeons should become thoroughly comfortable performing the procedure and completely familiar with the surgical approach and instrumentation before performing the procedure under local anesthesia.

When using local anesthesia, avoid injecting fluid into the carpal tunnel as it may obscure endoscopic visualization. The majority of local anesthesia should be administered subcutaneously in the wrist crease between the flexor carpi radialis and flexor carpi ulnaris. The remainder is administered along the track of the incision and superficial to the transverse carpal ligament.

OPERATIVE TECHNIQUE

IDENTIFY AND MARK KEY LANDMARKS

Before tourniquet inflation, outline the following structures with a sterile marker:

- Flexor carpi radialis (FCR)
- Flexor carpi ulnaris (FCU)
- Palmaris longus (PL, if present)
- Hook of the hamate (HH)
- A line from the middle wrist crease to the base of the ring finger
- Select one of the wrist flexion creases and mark a 1-2cm transverse line between FCR and FCU. [Figure 1] Use the proximal wrist crease for thinner soft tissue, or the distal crease if a cosmetic result is desired.

SKIN INCISION

Create a 1-2cm transverse incision in the marked crease. [Figure 2] Use gentle spreading dissection to protect small nerves and superficial vessels. Control bleeding with electrocautery. If present, retract the palmar cutaneous branch of the median nerve and palmaris longus radially.

FASCIA EXPOSURE

Elevate the forearm fascia with forceps and create a transverse U-shaped window. [Figure 3] Keep the median nerve protected as it lies directly beneath the fascia. Avoid traction on the ulnar neurovascular bundle to reduce neuropraxia risk.

Lift the fascial flap to expose the proximal carpal tunnel. Identify the median nerve and confirm orientation relative to Guyon's canal before proceeding.

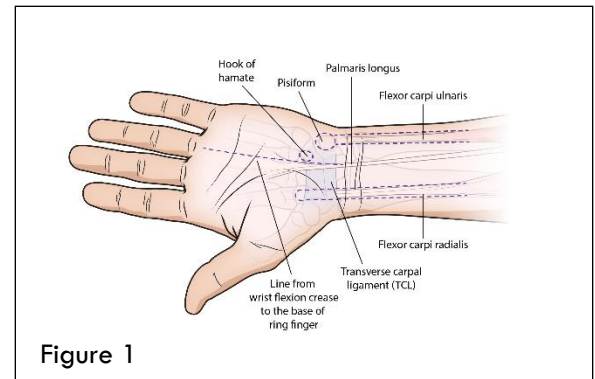


Figure 1

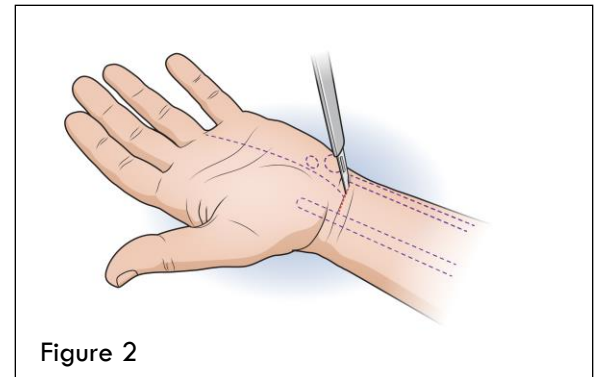


Figure 2

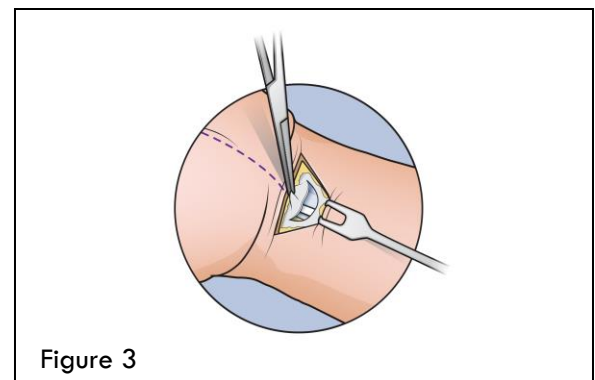
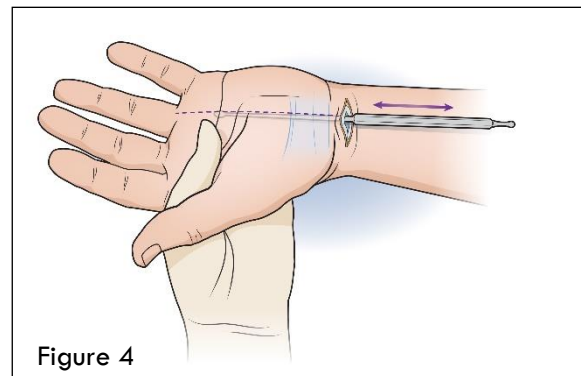


Figure 3

PREPARE THE CANAL

Use the TunnelVision™ synovial elevator to create a working path. [Figure 4] Direct the elevator toward the base of the ring finger, staying just radial to the hook of the hamate. Advance until coarse transverse fibers of the ligament are encountered. Confirm distal reach by palpation in the palm.

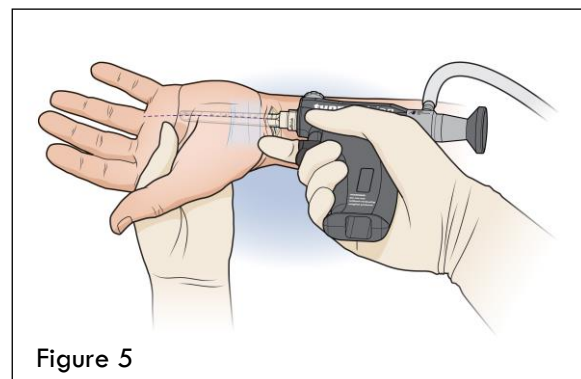
Dilate the tunnel sequentially with the small, medium, and coequal dilators until the passage accommodates the blade assembly.



INTRODUCE THE BLADE ASSEMBLY

Check the blade for smooth extension and retraction. With the wrist in slight extension, insert the blade assembly along the prepared path, maintaining close contact with the undersurface of the ligament. [Figure 5]

Advance toward the distal tunnel while keeping the window pressed against the ligament. Confirm a safe ulnar corridor by visualizing transverse fibers without neural structures before deploying the blade.

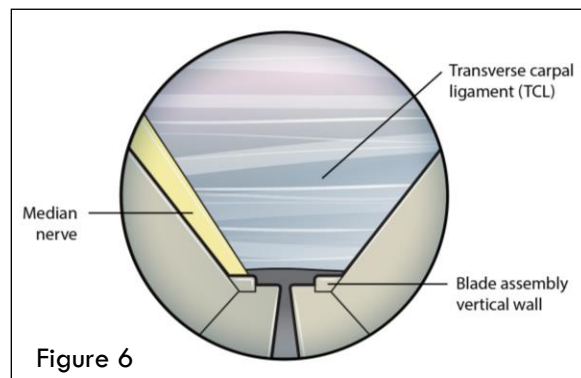


POSITION AT THE DISTAL LIGAMENT EDGE

Palpate the transition between the ligament and the fatty tissue of the palm. Align the distal wall of the viewing window with this edge. Use the centimeter depth markings on the blade assembly to confirm insertion depth.

Visualize the median nerve within the canal. [Figure 6] Confirm that the nerve is fully out of the viewing window before proceeding. If any portion of the nerve or other sensitive tissue is visible in the cutting corridor, adjust the instrument position until only the transverse carpal ligament fibers occupy the field.

If needed, partially elevate the blade as a preview to confirm where the dissection will begin. Proceed only once visualization of the ligament is clear and the nerve is excluded from the viewing path.



RELEASE THE LIGAMENT

Position the blade at the distal edge of the transverse carpal ligament. Elevate the blade and withdraw the assembly to divide only the distal half of the ligament. [Figure 7] Retract the blade completely and visually verify that the distal fibers are fully released. If any fibers remain, free them before proceeding.

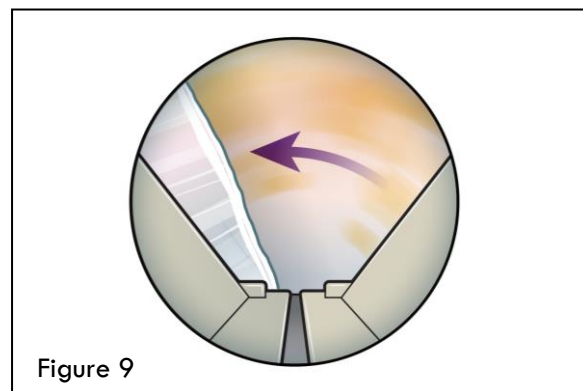
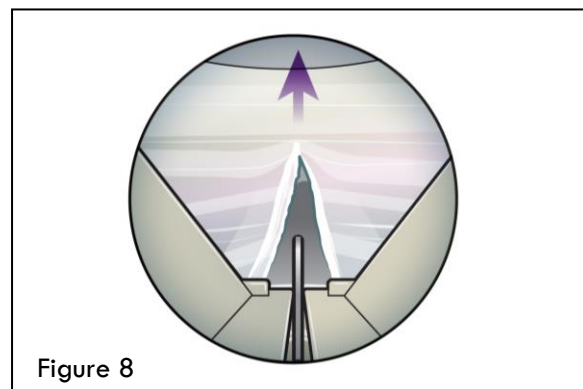
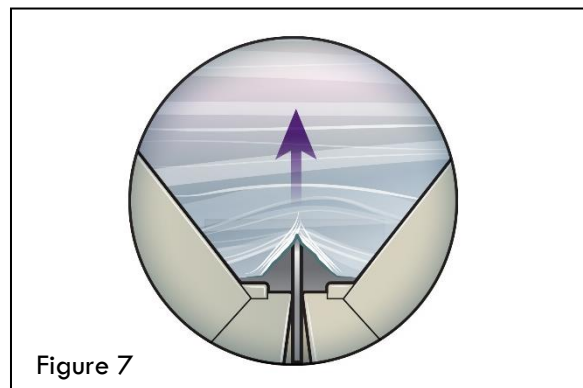
Reinsert the blade assembly along the same path. Elevate the blade again and divide the proximal half of the ligament, continuing the retrograde cut toward the wrist incision. [Figure 8] Retract the blade fully and inspect for residual fibers. Release any that remain until a continuous gap is visible through the full length of the ligament.

Finally, rotate the retracted blade assembly within the tunnel to inspect both cut margins and confirm complete release before removing the instrument. [Figure 9]

Using tenotomy scissors, release the forearm fascia proximal to the skin incision. Avoid the median nerve. If applicable, release the tourniquet.

CLOSE THE WOUND

Close the skin with an intracuticular suture for optimal cosmetic result. Apply a hand and wrist dressing that allows full thumb mobility. Encourage early finger motion. Limit heavy activity for 4–6 weeks; return to work varies by patient.



TROUBLESHOOTING GUIDE

Symptom	Fuzzy, foggy, or no image	Blade remains elevated	Trigger binds or sticks
Solution	1) Disassemble and dry the camera coupler to endoscope interface with isopropyl alcohol or anti-fogging agent and a sterile cotton swab. If the image remains poor, continue.	1) Leave the blade assembly inside the surgical site.	1) Clean accumulated debris in the handpiece per the IFU, paying particular attention to the area around the trigger and the trigger through hole on the bottom of the handle. If the trigger remains sticky, return the handpiece to Hand Biomechanics Lab for repair.
	2) Apply anti-fogging agent to endoscope tip and wipe dry. Allow device temperature to equalize with patient's body (~45 seconds). If the image remains poor, continue.	2) Loosen the locking screw on the handpiece. If the blade remains elevated, continue.	
	3) Absorb excess fluid inside the surgical site using a sterile cotton swab. If the image remains poor, return the endoscope to Hand Biomechanics Lab for repair.	3) Remove the endoscope from the handpiece. If the blade remains elevated, continue.	
Prevention	Store the endoscope in the protective Sterile Tray between procedures. Air dry the endoscope, then assemble the system to prewarm it prior to the procedure. Dipping the system components in room temperature sterile water or saline for approximately 1 minute will help equalize temperatures and prevent image problems.	4) Separate the blade assembly from the handpiece. If the blade remains elevated, leave the blade assembly in place and convert to an open procedure.	During cleaning, depress and release the trigger multiple times. Before surgery, verify proper function and ensure the blade elevates and retracts correctly.
		Before surgery, verify proper function and ensure the blade elevates and retracts correctly.	

Users and/or patients are required to report any serious incidents to Hand Biomechanics Lab as well as the Competent Authority of their Member State or the relevant local regulatory authority where they are located.

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Sterilization Tray Made in China

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